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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,041	10/30/2003	Julia Coronella-Wood	5051.057	7846

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,041	CORONELLA-WOOD, JULIA	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Coronella-Wood, Julia
Pending Claims: 1-11

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, as specifically drawn to an isolated polynucleotide encoding a breast cancer-specific antibody fragment including SEQ ID NO: 1, classified in class 536, subclass 23.1.

II. Claims 4-6, as specifically drawn to an isolated polynucleotide encoding a breast cancer-specific antibody fragment including SEQ ID NO: 2, classified in class 536, subclass 23.1.

III. Claim 7, as specifically drawn to an isolated antibody or antibody fragment that binds to breast cancer cells and contains the amino acid sequence of SEQ ID NO: 3, classified in class 530, subclass 387.1.

IV. Claim 8, as specifically drawn to an isolated antibody or antibody fragment that binds to breast cancer cells and contains the amino acid sequence of SEQ ID NO: 4, classified in class 530, subclass 387.1.

V. Claim 9, as specifically drawn to an isolated antibody or antibody fragment that binds to breast cancer cells and contains the amino acid sequence of SEQ ID NO: 5, classified in class 530, subclass 387.1.

VI. Claim 10, as specifically drawn to an isolated antibody or antibody fragment that binds to breast cancer cells and contains the amino acid sequence of SEQ ID NO: 6, classified in class 530, subclass 387.1.

VII. Claim 11, as specifically drawn to a method for screening brest cancer cells, comprising the step of contacting said breast cancer cells with ONE antibody, classified in class 435, subclass 7.23.

(Upon election of Group VII, the applicant must choose **ONE** antibody SEQ ID NO from those listed in Claim 11, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

The inventions are distinct, each from the other because of the following reasons:

While the inventions of both Group I and Group II are polynucleotides, in this instance the polynucleotide of Group I is 1405 nucleotides in length, whereas the polynucleotide of Group II is 1424 nucleic acids in total length. Furthermore, the polynucleotide of Group I encodes two antibodies which differ from those encoded by the polynucleotide of Group II. Thus, the polynucleotides of Group I and II are structurally distinct molecules and function to encode four structurally distinct antibodies. Therefore, the polynucleotides of Groups I and II are patentably distinct.

Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for <u>one</u> discrete amino acid sequence or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search for <u>two</u> different polynucleotides, and different polynucleotide segments in the databases, in addition to searching the organic molecule databases would require extensive searching and review.

The antibodies of Groups III-VI includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such

as the antibodies of Group III-VI which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I-II and Group III-VI would impose a serious search burden since a search of the polynucleotides of Group I-II would not be used to determine the patentability of the antibodies of Groups III-VI, and vice-versa.

While the inventions of Groups III-VI are polypeptides, in this instance the polypeptide of Groups III-VI encompass different antibodies comprising different heavy and different light chains containing different constant and variable regions, and different framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus, the polypeptide of Groups III-VI are structurally distinct molecules and are patentably distinct.

Furthermore, searching the inventions of Groups III-VI would impose a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search for four different polypeptides, and different polypeptide segments in the databases, in addition to searching the organic molecule databases would require extensive searching and review.

The inventions of Groups III-VI and the invention of Group VII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of screening breast cancer cells as claimed can be practiced with another materially different product such as an antibody set forth in SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER